EXHIBIT E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	
	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Robin Bridges Civil Action No. 2:12-cv-00651	
Paula Kriz Civil Action No. 2:12-cv-00938	

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APRIL 14, 2016

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Oral sworn deposition of TIMOTHY BRIAN McKINNEY, M.D., held at DRINKER BIDDLE & REATH, LLP, One Logan Square, 18th and Cherry Streets, Suite 2000, Philadelphia, Pennsylvania, commencing at 8:40 a.m., before Margaret M. Reihl, a Registered Professional Reporter, Certified Realtime Reporter, and Notary Public.

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I N D E X

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E X H I B I T S

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(Documents marked for identification as McKinney Deposition Exhibit Nos. 1 through 4, inclusive.)

... TIMOTHY BRIAN McKINNEY, M.D., having been duly sworn as a witness, was examined and testified as follows ..

BY MR. RESTAINO:

Q. Good morning, Dr. McKinney. We met informally before the deposition started, but, formally, my name is John Restaino, and I'm representing the plaintiffs in this matter, so I'm here to take your deposition today.

Have you had your deposition taken before?

A. Yes, I have.

Q. Approximately how many times?

A. About 13.

Q. Okay. So you're fairly familiar with the process, just a couple of the key points. There may be some times when we'll need an estimate on your part, and nobody here wants you to guess. Stating the obvious, you can estimate the length of this table, but you'd have to guess the length of my dining room table.

This is not an endurance test. If you

had any coffee kicks in with its physiological response and you want to take a break, just call time out.

Again, it's not a memory test. If you need to refer to a document, by all means, go right ahead and do that. I can't imagine this happening, but if you don't understand my question, just ask me and I'll try to put it into less legalese and more Englishese for you.

There may be some times when counsel to your left will object to my question, and unless you're instructed not to answer the question following the objection, we're still entitled to an answer. And other times I may ask what in my mind is a yes or no question and then you say yes and then go on and state something further, at which point I may say move to strike everything after yes. I'm not trying to be disrespectful. We're each trying to keep this record as clean as possible.

But, again, the most important thing is you need a break or want a break, just ask for it and ask for any documents you may need to review.

Any questions?

A. No.

Q. Okay. Now --

MR. RESTAINO: Matt, did you want to say something?

MR. MORIARTY: When you get to the reliance list and the notice, I'll talk about it then.

MR. RESTAINO: I was going to say we marked prior to the deposition the notice to take deposition as McKinney-1.

MR. MORIARTY: Okay. So in no particular order, Dr. McKinney has not yet sent an invoice for his time, but he made some notes, and he has probably worked 33 hours between January 29th, 2016 and April 12th, 2016, okay.

We produced -- we have with us the binders that we sent, and we can duplicate the table of contents for this easily, or if the plaintiffs want it, we can reduce this material to a thumb drive. Some of it is literature. Some of it is company documents.

MR. RESTAINO: Thumb drive is always lighter.

MR. MORIARTY: Okay. The reliance list that he has, in looking through the materials

yesterday, there is a discrepancy of approximately eight to ten medical articles that are on the reliance list that were supposed to be sent to him and through my error were not. I have compiled a list of those articles and will be sending them to him at some point. So he's reviewed all but maybe eight of the medical articles that are listed in the reliance list, and he will get the other eight at some point.

In addition, there are some things not on the reliance list that were sent in the month of March, a report from a plaintiff's expert named Dr. Veronikis, V-e-r-o-n-i-k-i-s, I believe a deposition from Dr. Blaivas, depositions of Drs. Ostergard and Sepulveda about their Gynemesh PS POP opinions and then two medical articles about whether there is an association between malignancy and polypropylene mesh. One is from the Cleveland Clinic. The other is from the Mayo Clinic.

And then the last thing about the Notice of Deposition is that the plaintiffs asked for him to produce presentation materials, let's

just leave it at that. So Dr. McKinney had three laptops. We went through three laptops, one of which whirs and clicks, if you remember the days when laptops made those noises, and it was extraordinarily difficult for us to pick out the many PowerPoints that he has because of his teaching role. So we have to redouble our efforts on the response to that part of the notice and figure out which PowerPoints correspond to things in his CV about presentations about pelvic floor disorders.

MR. RESTAINO: Okay. During that conversation, they brought in coffee and water. Why don't we take a break and go off the record for a moment.

(Brief recess taken at 8:46 a.m.)

(Deposition resumes at 8:48 a.m.)

BY MR. RESTAINO:

Q. So we're back on the record. We have our coffee, had a discussion.

Dr. McKinney, have you seen the deposition notice?

A. I have.

Q. And if you notice that starting on Page

6 or so, there's a Schedule A with numbered Paragraphs 1 through 19, correct?

A. Correct.

Q. And after discussion with counsel regarding laptop and other issues, have you made a good faith attempt to produce that which has been requested and which is not being objected to?

A. Yes.

Q. And it is my understanding that you have brought an updated CV?

A. That is correct.

Q. And is there anything, in your opinion, germane to the litigation, i.e., regarding the product and/or polypropylene mesh in general that's been added to the CV?

A. No.

Q. Any additions to the CV that could impact your litigation -- or excuse me -- your testimony now or at the time of trial?

A. No.

Q. Okay. And no other changes to your CV?

A. No.

Q. Okay. Then we've also had the discussion regarding the reliance list. I'm not sure

how that's going to impact today's deposition, but it's noted and appreciated.

And then we marked your general report, and since the signing of your report on March 2nd, 2016, have you done any further work or research into this topic?

A. Just -- not in particular, no.

Q. Okay, and I should have said for purposes of litigation versus your professional life. So there isn't any addendum being written up or errata being written?

A. Not today, however, up until trial, I will be reviewing things and evaluating things that could be added to it.

Q. Okay. Counsel has been kind enough to give me an estimate of the time that you have spent, I believe, since January on this, and I believe it's approximately 33 hours.

Does that sound correct?

A. That is correct.

Q. And how much do you charge per hour?

A. 650.

Q. Prior to being -- when were you retained as an expert for Ethicon?

A. Pretty much at that point in January.
Q. Okay. And who contacted you first?
A. That would be Matt Moriarty.
Q. Prior to being retained as an expert for Ethicon, did you have an opinion regarding the safety and efficacy of polypropylene mesh when used in pelvic and/or vaginal surgery?
A. I did.
Q. And what were those opinions?
MR. MORIARTY: Objection, form.
Go ahead.
THE WITNESS: Since I continue to use polypropylene meshes for reconstruction, I felt that they were safe.
BY MR. RESTAINO:
Q. Okay. Since reviewing materials in your role as an expert for Ethicon, has that opinion changed?
A. No.
Q. Regarding your expert report, did you write this yourself?
A. Yes.
Q. Is there any portion of it that was written by anyone else and provided to you?

MR. MORIARTY: Objection. I think the drafting process is not allowed under the rules.

BY MR. RESTAINO:

Q. Okay. Let me withdraw that question, because I believe Mr. Moriarty is correct.

Did you have a research assistant or anyone else do your research of, say, for example, PubMed for articles, or did you do this work yourself?

A. I did the work myself.

Q. The articles that are referenced in your expert report and/or in your reliance list, did you obtain those articles -- did you obtain the titles of those articles on your own during any research, or were these provided to you by anyone?

A. A lot of them were provided to me from counsel.

Q. Okay. But did you do your own PubMed research at any point?

A. I did not. However, I have enough articles that my partner from my practice also has some things, but they were pretty much almost listed in here, repeats.

Q. I noticed in my review of your expert

report in preparation for today that many, if not most of the articles, are dated in early 2000s and up to and including 2011 and 2012 and very few from 2015, 2016.

Is there a reason for that?

A. Because I'm only an expert for the Gynemesh PS and Gynemesh doing the early portions as the expert for this product line.

Q. If, however, there was an article published in January 2016 regarding the mesh, the polypropylene -- monofilament polypropylene mesh itself, would you be aware of it?

A. I've read a lot of them. It depends upon which article it is.

Q. And I didn't mean to imply -- I'm sorry, I'm not playing any games -- that there is one, I'm just -- let me ask a foundational question.

Is it your custom and practice to review PubMed for articles germane to your medical practice as they're published, or do you subscribe to journals and get your information that way?

A. I subscribe to journals and meetings.

MR. MORIARTY: And let me just interject that you just reminded me of something because he was provided after his report was written

the Maher Cochrane review regarding POP mesh that I believe was published in 2016.

MR. RESTAINO: Okay. I think I have that to talk about a little later.

BY MR. RESTAINO:

Q. If we can turn to your expert report and turn to Page 3, the top paragraph. You write, "In addition to my public literature, when I was practicing full time my website had a discussion about vaginal repair with mesh, publications of the IUGA findings and a commentary on the FDA safety communication released in July, 2011, all to educate my patients and other doctors better."

Did I read that correctly?

A. Yes.

Q. Are you no longer working full-time?

A. I am no longer working full-time. I took a sabbatical for this year. I still hold my faculty appointment at Drexel University, still have fellowship in female pelvic medicine and reconstructive surgery. However, I needed for, I guess, financial reasons to close my private practice, in which I'm in the process of still doing that and reorganizing myself, still have a practice out of Florida as well.

Q. Okay. Regarding the commentary on the FDA safety communication released in July 2011 all to educate my patients and other doctors better, this was a website that you maintained?

A. Yes.

Q. And do you have any information on how many people actually read the website?

A. I wouldn't know, but I'm sure the IT people could probably figure that one out.

Q. Do you have any objective evidence that other physicians read your website?

A. Other than friends of mine saying that they liked my website and they were going to copy it, so, yes.

Q. And the friends of yours copying the format of the site, the kind of information you had there?

A. Yes.

Q. Okay. Now, there was, as you mention, a release by the FDA in 2011 of an "Update on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse: FDA Safety Communication."

Does that sound familiar?

A. Yes.

MR. RESTAINO: We'll go ahead and have that marked as McKinney next.

(Document marked for identification as McKinney Deposition Exhibit No. 5.)

MR. MORIARTY: I'm sorry, is that the 2011?

MR. RESTAINO: Yes. That's the 2011 website update versus the -- what I'll call the monograph that we'll get to in a little bit.

BY MR. RESTAINO:

Q. And, Doctor, have you seen this before?

A. Yes.

Q. If you look down on the first page about the middle of the page or so, there's a heading "Device," and then the first sentence says, "surgical mesh is a medical device."

Do you see where I am?

A. Yes.

Q. Do you agree that it was the intent of the implantation of mesh that it would be permanent in nature?

A. Yes.

Q. And did you tell your patients prior to

installing the mesh that the intent was that this would stay in them for the rest of their life?

A. Yes.

Q. On the next page, the second heading is "Purpose."

Do you see that?

A. Yes.

Q. And they state that "On October 20, 2008, the FDA issued a Public Health Notification and Additional Patient Information on serious complications associated with surgical mesh placed through the vagina (transvaginal placement) to treat POP and SUI."

Did I read that correctly?

A. Yes.

Q. And did you include the October 20th, 2008 notification on your website?

A. I can't remember. I don't recall exactly. I put a lot of things into it to educate everybody and whatever I was using, I tried to, to my best ability, give extra information to my patients. Usually before going to the OR, it took me close to an hour to end up getting through my informed consent, and that gives you an idea. Plus, I have a nurse that sets up all my OR cases, and she spends the extra time as

well. As well as it's all listed in my consent forms.

Q. And between 2008 and 2011 did you continue to maintain your website?

A. Yes.

Q. And do you maintain that website today?

A. Well, it's actually been updated. I had a new partner come on board, I guess it was 2011, Dr. Babin, and she ended up revising my old website, and that's when we included all the FDA material in there.

MR. RESTAINO: I'm going to go ahead and ask court reporter to mark the October 20, 2008 "FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence."

(Document marked for identification as McKinney Deposition Exhibit No. 6.)

BY MR. RESTAINO:

Q. Dr. McKinney, have you seen this before?

A. I have.

Q. And if you notice the heading in the middle of the page, "Dear Healthcare Practitioner." At

this time, do you recall how you became aware of this public health notification?

A. I do not.

Q. In situations like this when the FDA would issue a public health notification regarding something that is germane to your professional practice, would the FDA mail that to you or must you find this by on your -- through your own means?

A. I can't recall on this. I know through all of the connections through my membership to AUGS, my membership to AUA, I get notified on a lot of things. As well as I have a tickler in the computer that pops up anything to do with subjects I'm interested in.

Q. Are they alerts through NCBI, PubMed?

A. Yes.

Q. If you notice underneath it says under "Dear Healthcare Practitioner," it states "This is to alert you to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). Although rare, these complications can have serious consequences. Following is information regarding the adverse events that have been reported to the FDA and

recommendations to reduce the risks."

Did I read that correctly?

A. Yes.

Q. And this is issued October 20th, 2008, correct?

A. That is correct.

Q. Now, here we are in April of 2016. Is it your expert opinion to this date that the complications which can have serious consequences are, in fact, rare?

A. I should expand upon this because I've been involved with pelvic reconstructive surgery since the '80s, and any reconstructive work is not associated with a minimal risk of some complications. It doesn't matter whether it's using regular suture material, native tissue or mesh material, they all have their significant risk factors.

So, yes, I'm familiar with the fact that with all pelvic or reconstructive surgery or surgery, for that matter, there's risks and they have to be explained to the patient thoroughly.

Q. And at the same time regarding the risks with the transvaginal mesh, it is your opinion that these complications are rare in your hands, correct?

MR. MORIARTY: Objection to form.

Go ahead.

THE WITNESS: That is correct.

BY MR. RESTAINO:

Q. In fact, if we can turn to your expert report, Page 7 in the top paragraph, last sentence you talk about, if it fails excision or total explant needs to be done, but it is rare in my hands; is that correct?

A. Yes.

Q. How did you determine that it was rare in your hands? Did you do a retrospective analysis of your cases to see of the cases you have had since going into practice how many of them ultimately went on to develop these serious complications?

A. As in an education situation, which I am as a professor, I also have residents and fellows, and we do follow our outcomes, and so, yes.

Q. Is there an objective analysis of your outcomes?

A. There is an objective and subjective.

Q. Okay. And it's also your opinion that the infections associated with polypropylene mesh are also rare; is that correct?

A. That is correct.

Q. And how do you -- in the context of the pelvis and/or vagina of the woman receiving the polypropylene mesh, in that context, how do you define an infection?

A. Well, there's an initial postoperative time frame in which there would be, say, an abscess created probably from a hematoma that got infected and a drainage of that actual infection. I don't consider that a mesh complication or a mesh infection but as a normal -- normally abnormal event. Within any kind of pelvic surgery, there's a certain rate, if you've done a hysterectomy, you're doing reconstruction of cuff cellulitis and infections, that is, in my professional opinion, higher than the rates of infections of just graft alone without a hysterectomy and a cuff problem.

Q. Do you make a determination in that sense between contamination and infection?

A. Infection, it's kind of hard to -- I would say that every case of a vaginal surgery has contamination, and until we can totally sterilize the vagina, you can't. In fact, you'll see I have a paper on looking at sterilization of the vagina and immediately post prep, and you still have about a third

of the colonies of bacteria in the vagina after you totally prep the vagina. And after about two hours, you have the same amount of colonies that you began with. So it's evident that the vagina is not a sterile environment.

Q. Which is not unexpected considering the anatomy and physiology, would you agree?

A. That is correct.

Q. And would you expect, therefore, that with local bacteria present that the passage of any foreign material, for example, polypropylene mesh could, in fact, become contaminated with bacteria?

A. I think that your incision fields, whether it be native tissue, whether it be putting a suture in and tying it securely up against, say, the muscle area is going to cause a necrosis of the tissue, so that leaves you with niduses of infection all across the board.

Q. You use the term native tissue, and just so that the record is clear, can you share with the Court what you mean by "native tissue."

A. Native tissue meaning that which is of the patient's own origin, which has gone through pathological changes or trauma, either from

childbearing, from exposure to chronic constipation, but tears in the support. So you're using the patient's own tissue to repair itself, to try to return it back to its anatomical position.

Q. The patient's own physiologically alive tissue, correct?

A. You would hope they are alive, but they could be scarred, they could be lack of blood supply, and they could be just fibrosis. But, yes, it's what the patient has to offer when you're doing surgery.

Q. And the patient's tissue, native tissue has the benefit of the patient's immune system with blood and white blood cells, lymphocytes, et cetera, passing through it, correct?

A. Not necessarily, again, because of the fact that some of these tissues have been traumatized and damaged, and part of the healing process is scarification, and some of the scars do not have a neovascularization, they don't have a blood supply in them.

Q. They're not necrotic tissue, though, correct?

A. They're not.

Q. They're living tissue?

A. They're within the living body, yes.

Q. And you also mentioned a single suture, I believe, to tack up the woman's own tissue?

A. I was using that as an example of tying down a single stitch to tie off and repair back to say its muscle attachment, as in the pubocervical fascia, which is the support for the anterior wall, back to the lateral side wall muscles, the levator muscles. When you tie that down, you're tying it down significantly enough that it will stop the blood supply to that muscle area, and thus you decrease the blood flow, you decrease the ability for that tissue to be still living.

Q. And in that sense, how many sutures are used?

A. It depends upon the patient's needs, but definitely not just one.

Q. Can you give an estimate in the average patient approximately how many stitches you think you'd put in?

A. For which surgical procedure? Say, for the anterior compartment, which would consist of cystocele, the pubocervical fascia usually tears free from up around the ischial spine area, so you're

starting at the apical region and tying down to the iliococcygeal muscle, obturator internus muscle area, putting stitches there and doing basically a paravaginal repair. So you're putting several stitches to support it if there's a defect there.

Q. The average stitch, the average suture material, if it's whatever, 4.0 Prolene or whatever you may be using, it's approximately 12 inches long before you use it and cut it?

A. Approximately.

Q. And would you agree that the average stitch that you put in is after being cut maybe a centimeter in length?

A. Yes.

Q. And if we were to put in a total of 20 stitches, doing that type of repair, so we'd have 20 centimeters, approximately, correct?

A. That is probably correct.

Q. Do you know how many yards of tissue make up the average polypropylene mesh?

A. I do not.

Q. Would you be surprised if it was hundreds?

MR. MORIARTY: Objection. Go ahead.

THE WITNESS: No.

BY MR. RESTAINO:

Q. Is it your understanding there's a lot more polypropylene mesh -- polypropylene fibers present in the mesh than there is in individual stitches?

A. Yes.

Q. And if an individual stitch was to become irritable and start to extrude or be spit, that that's a different pathological response to a large portion of mesh being spit or extruded, would you agree?

MR. MORIARTY: Objection, form.

Go ahead.

THE WITNESS: I don't believe so.

BY MR. RESTAINO:

Q. Have you ever had skin sutures that needs to be spit and nipped and taken out?

A. Yes.

Q. Is that the same as when vaginal mesh erodes through the vaginal epithelium?

A. All depends.

Q. On what?

A. The size of the exposure, whether it's a true through and through or whether there's a layer

that's attempting to be healed over the top of it.

Q. Now, with the passage of the stitch, stitches and/or the mesh through this clean contaminated vagina, if, in fact, the mesh becomes contaminated with bacteria that at any time when it's present, and especially during times of immunosuppression, that -- or those bacteria can multiply and become a clinically significant infection, wouldn't you agree?

MR. MORIARTY: Objection, form.

Go ahead.

THE WITNESS: I don't know how to answer that. That's why we're usually taught as surgeons that -- to practice good technique as far as making sure you have good hemostasis so that there's no nidus for these bacteria to take hold, also to make sure you try your best to decrease the population of bacteria, thus giving some prophylaxis of antibiotics.

Plus, at the end of any of these type of surgeries, even any native tissue or whatever, we usually do an irrigation, whether it be with an antibiotic solution or not to, as we say, dilution is the solution to pollution. We try

to irrigate out as best as possible the majority of those bacteria that could be in there and then try to decrease the dead space, as it's called, so pack the vagina, put as much closure to the area so that bacteria can't move into positions.

BY MR. RESTAINO:

Q. Once the mesh is implanted and all incisions are sutured closed, then, in fact, the mesh is protected from any antibiotic wash that you might be using within the vagina itself, correct?

A. Well, usually the spaces as irrigated as particularly your technique. Mine is before you end up closing that, you end up in giving an extra little dousing to try to end up closing. But then after you've closed it, yeah, you're not doing anything more to irrigate out that spot.

Q. Inasmuch as the polypropylene mesh is a foreign material, it does not have access to the body's immune system within the blood, correct?

A. The graft material itself, no, but the body's own tissue that would be involved in this has the ability to end up taking care of infections within this inert area.

Q. And so to avoid any confusion when we're discussing this topic now or throughout the course, you said that you just -- and paraphrasing -- that the body's own tissue has ways of dealing with infection, but does the body's own tissue have a way of dealing with polypropylene mesh contamination which occurs through the passage of the mesh through the vagina into its anatomic space?

MR. MORIARTY: Objection, form.

Go ahead.

THE WITNESS: I believe that the body does have an ability to take care of any infections. That's why the mesh has porosity. The body has macrophages that can end up migrating into that mesh area to end up having its own ability to take care of the bacteria that's around there.

BY MR. RESTAINO:

Q. And have you heard of the body's response of forming a biofilm around any foreign material that's implanted?

A. That was probably more associated with your Type II type materials, such as Gortex in the past that they form a seal around it and wall it off, rather

than incorporate the tissue or the matrix, as I call the graft material, into the fascia. So that's my thought process. You may have different explanation of what your biofilm is.

Q. So is it your expert opinion that the mesh being implanted today will not develop a biofilm around it?

MR. MORIARTY: Objection.

THE WITNESS: Again, I need your definition of what you're calling biofilm.

BY MR. RESTAINO:

Q. Any type of tissue material that, in fact, incorporates itself around and within the mesh and continuing that, if, in fact, the mesh had become contaminated during insertion through the clean dirty vagina and the mesh, biofilm mesh -- and the biofilm encompassing the bacteria also.

A. I would say that the body will have fibroblasts that migrate into the mesh matrix. There will be macrophages in the normal body's response to any kind of infection will occur as well within the graft materials.

Q. Now, we briefly touched upon the fact that in 2011, the FDA sent an update to their warning

from 2008; is that correct?

A. That is correct.

Q. And I believe you have that in front of you already marked as an exhibit?

A. Yes, Exhibit 6.

Q. And you discussed this update in your expert report, correct?

A. I did.

Q. And if you look at the second page, the fourth paragraph down?

MR. MORIARTY: Are you talking about Exhibit 5 or Exhibit 6 now?

MR. RESTAINO: I'm talking about the July 13, 2001 update on serious complications.

MR. MORIARTY: Well, Exhibit 5 has date issued July 13th, 2011, and Exhibit 6 has two dates, one being July 13th, 2011 and the other October 20th, 2008. I just want to know which exhibit you're looking at, 5 or 6.

MR. RESTAINO: I'm looking at 5, the one that's date issued July 13th, 2011, and it's confusing by that FDA document.

MR. MORIARTY: And, I'm sorry, page, please.

BY MR. RESTAINO:

Q. The second page, fourth paragraph.

And it starts off with, "The FDA is issuing this update."

Do you see that, sir?

A. Yes.

Q. Read the entire sentence, "The FDA is issuing this update to inform you that serious complications associated with surgical mesh for transvaginal repair of POP are not rare."

And not rare is bolded; is that correct?

A. That is correct.

Q. Now, you've discussed this safety update in your expert report, correct?

A. I did.

Q. Do you state in your expert report that, in fact, the FDA changed from 2008 when it said the serious complications are rare to 2011 when they come out and say these serious complications are not rare?

A. The question again?

Q. Do you state in your expert report that's signed March 2016 that this July 2011 safety update from the FDA indicates that serious complications associated with surgical mesh for

transvaginal repair of POP are not rare?

MR. MORIARTY: Objection, form, and if you have a specific spot in his report that you're asking about, fine, but, otherwise, you can just review it.

BY MR. RESTAINO:

Q. If I may assist you, sir, if you look on Page 7, the top paragraph described the need to excise mesh because of serious complications as rare in your hands. That's one place where it's listed.

A. And, again, your question is did I mention in my report the change?

Q. Okay. Let's go with that question.

Do you mention in your report that the FDA changed between 2008 and 2011 from the serious complications are rare to serious complications are not rare, with not rare being, in fact, bolded?

A. I didn't specifically mention that. I just mentioned the FDA reports. I believe that with any POP surgery that there are major complications, and that's kind of why I ended up going into this field in particular was because in my residency program, statistics were anywhere from 20 to 40% dyspareunia rate afterwards and the shrinkage of the vagina from

native tissue repairs that were being done at that time. So they were not reported to the FDA because it was suture techniques.

But with having a material and with that being able to be put through the MAUDE database, you get the data. With native tissue there is no compilation, and that's why the FDA is now requesting a 522 to be done.

Q. Continuing on, looking at this paragraph, the next sentence is, "This is a change from what the FDA previously reported on October 20, 2008. Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and may expose patients to greater risk."

Did I read that correctly?

A. I'm sorry, I didn't see where we were -- oh, it's a continuation?

Q. Yes, I'm sorry. I'll just give you a moment, and you can read that entire paragraph to yourself, if you'd like.

A. Yes.

Q. I was not able to find anywhere in your expert report anything related to the FDA indicating

that it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP.

Is it your opinion that the FDA is incorrect with their statement here?

A. There have not been a tremendous amount of good literature, studies looking at prospective, randomized studies between, say, native tissue and non and, therefore -- and so they're looking for further data, so there's a question out there that is it as effective, is it necessary.

We know as surgeons in the field of reconstruction that there's been frustration for years. There's nothing worse than having a patient, especially being a specialist, having a patient come to you, you do a surgical repair and it breaks down, and you think that you're doing the right thing, you've done everything exactly like you do for the next patient over, and it falls apart. It's been a frustration, and it's why in general surgery they were frustrated with failures of their native tissue repairs and why they augmented with hernia meshes to begin with.

That's why we were looking for some ability to make our patients have a better quality of

life and not have to deal with multiple operations in their life or decrease in their problem, so we're still in the quest of that.

Q. Does your expert report state anywhere that the use of transvaginal mesh may expose patients to greater risk than traditional non-mesh repair?

A. Does not.

Q. If you continue down on that page, second full paragraph from the bottom it starts "From 2008-2010."

Do you see that?

A. Yes.

Q. "The most frequent complications reported to the FDA for surgical mesh devices for POP repair include mesh erosion through the vagina (also called exposure, extrusion or protrusion), pain, infection, bleeding, pain during sexual intercourse (dyspareunia), organ perforation, and urinary problems."

Did I read that correctly?

A. Yes.

Q. And mesh implants can, in fact, erode through the vaginal epithelium, correct?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: There are technique pieces to it, but we've made the incisions not deep enough or done enough damage to the vaginal tissue, the vaginal tissue may disappear, it may slough off, it may die.

BY MR. RESTAINO:

Q. And forgive me, I didn't mean to interrupt you, sir.

And I think what you just said alludes to the surgical technique that was utilized, but it's also true that an inflammatory response to the polypropylene mesh can result in degradation of the epithelium leading to erosion, correct?

A. That's never been proven. It's a higher probability that we've caused some significant changes to the structural integrity of that skin.

Q. In any given procedure where, ultimately, the mesh erodes through the vaginal epithelium, how do you know if that was due to surgical technique or the inflammatory response to the mesh?

A. You don't.

Q. So if one was to say that mesh extrusion or erosion is due to the surgical technique, one would,

in fact, be speculating, would you agree?

MR. MORIARTY: Objection to form.

Go ahead.

THE WITNESS: Surgery is not a perfect environment. I mean, there are -- when you're finished with the surgery, you've got blood products that are definitely still within that environment, so the natural tendency for the body is to end up expelling any of those waste products from our own body's ability to get rid of what's there.

So sometimes the suture bridges that we've created to close is opened up to drain that. When that opens up, they don't necessarily close down appropriately, and that may be the exposure that you end up having of the graft, not so much that there's an infection of the graft or an inflammatory response of the graft that causes it. It's just that the actual body's response to it, it opened up, and it didn't heal over quite as yet.

BY MR. RESTAINO:

Q. Well, the body's response in that regard

would be an inflammatory response, correct?

A. Not so much to the material itself but just to the opening of the breach of the skin.

Q. Okay. Could you define for us dyspareunia?

A. It's painful intercourse.

Q. Have you heard of the term hispareunia?

A. Yes.

Q. Is that just recently used, or is that something that has been used by the urogynecological surgeons for some time?

A. It's been used since the '80s. We used to laugh about it, particularly with some of the permanent suture materials, they'd have some problems that way or from doing laparoscopic hysterectomies using stapling devices they developed hispareunia. That was in the early '90s.

Q. And for the Court and for the record, what you are referring to or what we're referring to with this term, hispareunia is that the pain that might be experienced by the male during sexual intercourse; is that correct?

A. That is correct.

Q. Now, in your -- I think we've already

touched upon this, I just want to clear it up, but in your expert report, you refer to the mesh erosions as essentially a wound complication, do you not?

A. Like in other surgeries, yes.

Q. However, the FDA links mesh erosion as with some of the serious complications associated with the use of mesh, correct?

A. They are saying that.

Q. Do you consider mesh erosion into the vagina to be a serious complication?

A. Not necessarily.

Q. Can it be?

A. Like in any surgical situation, there are grades of a problem and which need to be addressed. As anything that needs to be addressed, surgical intervention probably becomes more of a serious.

Q. If we turn to Page 3 of the 2011 short update letter that we've been referring to and look at -- you see there's three bullet points on top and then a paragraph that begins with "The FDA's literature review." Do you see where I am, sir? In essence, the third paragraph down.

A. Mm-hmm.

Q. It says, The FDA's literature review

found that erosion of mesh through the vagina is most -- is the most common and consistently reported mesh-related complication from transvaginal POP surgeries using mesh. Mesh erosion can require multiple surgeries to repair and can be debilitating for some women. In some cases, even multiple surgeries will not resolve the complication.

Did I read that correctly?

A. Yes.

Q. The FDA there in talking about these mesh-related complications using mesh are talking about something entirely different than a wound complication; are they not?

A. It incorporates a number of aspects besides just the wound complication, wound opening. With any -- again, I'll go back to with any kind of reconstructive surgery, native tissue wise, there can be similar multiple operations to return a person back. I get those referrals because I've got a vagina on native tissue that's almost closed completely. It's agglutinated from somebody doing an operation to close it. Those are not very uncommon as well, and that was the frustration that I felt was -- I'll go back.

It's just a -- it's a known problem

within it, and I'm starting to see it more and more now that we're going back to doing more native tissues that I'm seeing short vaginas, shrunken vaginas, narrowed vaginas that require surgical intervention to rebuild them.

Q. You would agree that as of July 2011, the FDA indicating that the serious complications from mesh surgery exceeds those with the native tissue?

MR. MORIARTY: Objection. Go ahead.

THE WITNESS: There aren't any good studies that would equate that.

BY MR. RESTAINO:

Q. Okay. The next paragraph down start off with the words "Mesh contraction."

Do you see that? So it would be the fifth.

A. Yes.

Q. Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA since the October 20th, 2008 FDA Public Health Notification. Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening

and vaginal pain.

Did I essentially read that correctly?

A. Yes.

Q. Now, this is the July 2011 safety update, but in your March 2016 expert report, you state your opinion that mesh does not contract; is that correct?

A. I do.

Q. And what is the objective basis for your belief that mesh does not contract?

A. I believe that the mesh is inert and it doesn't contract, but the body's scar tissue which develops around that can end up causing a tightening of the area, much like native tissue scarring can end up doing it, or people react to different things different ways. Putting in, say, an earring, normally most people have no problems with it. Some people develop keloids. It's a healing process that is a scarification that the body's reaction to surgery can end up causing, whether it be native tissue, whether it be something placed in to the vagina, such as mesh.

Q. Now, you started off your answer by saying I believe that the mesh is inert and my question is what objective basis are you relying upon for your

opinion that mesh itself does not contract?

A. In that my own personal experience, as well as that mesh doesn't change its shape as such.

MR. RESTAINO: I would like to have marked as McKinney next, article titled "Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs." Lead author Klinge, published in the European Journal of Surgery in 1998.

(Document marked for identification as McKinney Deposition Exhibit No. 7.)

BY MR. RESTAINO:

Q. Doctor, have you seen this article before?

A. I believe at one time I have.

Q. Do you recognize the name Klinge, K-l-i-n-g-a?

A. G-e.

Q. G-e, I'm sorry.

A. No.

Q. Do you know if Dr. Klinge is an expert for plaintiffs in the litigation?

A. I don't recall.

Q. Probably a question I should have asked

at the beginning of the deposition, did you review any of the plaintiff expert reports prior to writing your expert report?

A. I did not, actually.

Q. In any search that you may have done yourself in preparation for developing your opinions and/or writing your report, did you conduct PubMed search using, for example, the terms polypropylene mesh -- well, let's just stick with that, polypropylene mesh?

A. I did not.

Q. As you sit here today, do you know if Dr. Klinge has published 126 articles on mesh?

A. I am not familiar with the volume of work that he has.

Q. And he's not referenced, as far as I can see, in your expert report nor in your reliance list, correct?

A. More than likely not.

Q. Have you published articles on polypropylene mesh?

A. Yes, I have.

Q. And can you share with us how many are published in peer-reviewed publications?

A. None.
Q. Is it more than one?
A. I said none.
Q. Oh, none, I'm sorry. Forgive me.
MR. RESTAINO: Matt, we've been going for about an hour, want to take a minute or two.
MR. MORIARTY: Yes, we can take a minute or two.
(Brief recess taken at 9:48 a.m.)
(Deposition resumes 9:53 a.m.)
BY MR. RESTAINO:
Q. Doctor, before we went on break, I have handed to you this article by Dr. Klinge titled "Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs," and if you would just look at the abstract, you see that right from the get-go the objective of this study was "to assess the extent of shrinkage of meshes used for hernia repair."
Did I read that correctly?
A. Yes.
Q. And then if you look down -- by all means, take your time to review the entire abstract or, for that matter, any part of the article, but you see

their conclusion is that "meshes that contain a lot of polypropylene shrink to about 30%-50% of their original size after 4 weeks, requiring an overlap of at least 3 cm if implanted subfascially. Reduction in the polypropylene content decreases both the inflammatory response and the shrinkage. Meshes with big pores are less likely to fold and improve compatibility."

Did I read that correctly?

A. Yes.

Q. Were you aware of this opinion prior to you writing your expert opinion wherein you write that the polypropylene mesh does not contract?

MR. MORIARTY: Objection, form.

Go ahead.

THE WITNESS: Again, this is a dog study, not a human study. I'm not sure how they determined that the -- whether the healing process was the part that was involved more so than the polypropylene shrink. It's my opinion that it's not the material itself that shrinks, it's the live tissue that causes a decrease in the surface area, and that's why we put in things loosely, such as with the slings.

BY MR. RESTAINO:

Q. Turn to your expert report Page 17, the second paragraph, and therein you write on the fifth line on the right, "there is no literature to support clinically significant mesh degradation in humans."

Did I read that correctly?

A. Yes.

Q. And what do you mean when you say "clinically significant mesh degradation"?

A. That could ever be affecting the integrity of the graft material.

Q. And now in the next paragraph, the third line starting towards the right you start off by saying, "Furthermore, the mesh does not shrink."

Do you see where I am now? It's the third paragraph down where you start off with, "Nor have I seen a problem with Prolene Soft," that paragraph.

A. Yes.

Q. Okay. The third line on the right you write, "Furthermore, the mesh does not shrink."

Do you see that there?

A. Yes.

Q. And "it's the scar tissue that forms after any pelvic surgery that contracts, and tissue

incorporating into implanted mesh is no exception, but the mesh itself does not contract. Prolene is inert."

Did I read that correctly?

A. Yes.

Q. Now, there aren't any references for those opinions listed there, correct?

A. Correct.

Q. Can you give us objective evidence of what you're relying upon for your opinion that first the mesh does not shrink?

A. Just my personal experience with it that -- and from numerous communications and educational talks through -- from meetings, but mainly my personal experiences.

Q. One of these table questions, can you estimate for us the number of cases where you have implanted polypropylene mesh either as a resident and in the abdominal wall for hernia repair or a resident through today in the pelvis and/or vagina?

MR. MORIARTY: Including slings?

MR. RESTAINO: Yes, including slings, let's include slings.

THE WITNESS: Definitely thousands of procedures.

BY MR. RESTAINO:

Q. And of those procedures, can you give us an estimate of how many times you've had to take the mesh out?

A. As a complete explant, probably less than ten.

Q. 10% or ten cases?

A. Ten cases. And on the referral basis, well, for other people's mesh cases.

Q. If we go back to the Klinge paper, first page, you see the heading "Introduction"?

A. Mm-hmm.

Q. And four lines down on the right-hand side he writes, "The appearance of dislocated mesh in bladder and bowel (5, 6, 13) as well as the histological examination of removed meshes have shown that the incorporated alloplastic material is not inert and causes a constant inflammatory response, folding and shrinking."

Did I read that correctly?

A. Yes.

Q. Dr. Klinge has the references there I mentioned 5, 6 and 13, correct?

A. Correct.

Q. If you look at his references 5, 6 and 13, can you tell us whether you reviewed those articles in preparation for writing your expert report?

A. I can't recall.

Q. Is it fair to say that you do not opine upon those articles in your expert report as for evidence, in fact, of shrinkage and an inflammatory response?

A. That's correct.

Q. Was your residency in gynecological surgery or urogynecological?

A. My residency program was in gynecology.

Q. And did you do a fellowship after that?

A. I did.

Q. And today do you hold yourself out as a gynecological surgeon or a urogynecological or both?

A. Both.

Q. During any part of your residency and/or fellowship, did you also train, go through general surgery?

A. I did not, other than rotations in general surgery.

Q. Would that be as intern, resident, medical student?

A. Intern.

Q. As a surgeon would you agree that the vagina is a complex anatomical and physiological environment, unlike any other part of the body?

A. Yes.

Q. And, as such, would you expect the vagina's postoperative response to be identical to the response to other body parts, for example, the back?

A. I couldn't comment on the back.

Q. Okay. Well, you know, where I'm going with this, and it will save a little bit of time, as a segue to this answer, you noted during glancing at the Klinge report that this study was done in dogs, correct?

A. Correct.

Q. In your review of internal documents and medical literature, have you ever seen a study where they took the mesh and they put it in the vagina of a rat or a dog?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: Gosh, I know there have been studies done with placing, but not so much in rats but dogs.

BY MR. RESTAINO:

Q. In fact, it would have to be a very, very small little mesh to be used in either the canine or the murine vagina, correct?

A. Very much so.

Q. So would it surprise you to learn that most, if not all of the studies that have looked at the inert aspect of mesh and/or contractability of mesh and/or safety of mesh have been done in animals by putting it subfascially on their dorsum?

A. It doesn't surprise me.

Q. Now, as a physician and surgeon, you took general anatomy in medical school, correct?

A. Yes.

Q. Is the dorsum of the back anything at all like the complex environment of the human vagina?

A. No.

MR. MORIARTY: Objection.

Go ahead.

MR. RESTAINO: I'm sorry, Matt. Were you done?

MR. MORIARTY: I'm done.

BY MR. RESTAINO:

Q. I'll come back to that in a moment. If

you turn back to the 2011 FDA safety update, you see the bottom full paragraph on Page 2 it starts off with "In order to better understand the use of surgical mesh."

Do you see that?

A. Yes.

Q. And then it's "surgical mesh for POP and SUI, the FDA conducted a systematic review of the published scientific literature from 1996-2011 to evaluate its safety and effectiveness."

Did I read that correctly?

A. Yes.

Q. And did you do a systematic review of the literature prior to writing your expert report?

A. I looked over a significant portion of it that was, again, provided, and that was from definitely covering that time period.

Q. The next sentence there from this paragraph states, "The review showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair."

Did I read that correctly?

A. Yes.

Q. And is that what your review of the literature revealed?

A. There are varied studies in there that show differently.

Q. In your expert report did you note anywhere that the FDA's analysis of the literature indicated that repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair?

A. I did not mention that.

Q. Below that paragraph the FDA writes, "In particular, the literature revealed that: Mesh used in transvaginal POP repair introduces risks not present in traditional non-mesh surgery for POP repair."

Did I read that correctly?

A. Yes.

Q. Do you agree or disagree with the FDA in that statement?

A. I sort of disagree in the fact that most of the risk factors for any POP surgery are very similar to those with graft materials and that the traditional non-mesh surgeries have the added aspect of increased risk of recurrences which adds another dimension to the entire game of repair, which means

that you're going in on scarred, changed anatomy and trying to end up bringing back some quality of life for these patients.

Q. And what is the objective basis for that opinion?

A. My personal experience.

Q. On the next page, Page 3 of 6, the third bullet point down from the top the FDA writes, "while transvaginal surgical repair to correct weakened tissue," do you see where I'm reading from, sir?

A. Yes.

Q. "Between the bladder and vagina (anterior repair) with mesh augmentation may provide an anatomic benefit compared to traditional POP repair without mesh, this anatomic benefit may not result in better symptomatic results."

Did I read that correctly?

A. Yes.

Q. And do you agree or disagree with the FDA with that statement?

A. Again, that's why they're ending up having the 522s going on to be able to evaluate better because there really is not a tremendously wonderful literature out there, and they're basically emphasize

anatomical benefit may not. It may indeed be better and -- the anatomical benefit, yes.

Q. And what is the objective basis for your belief that it may, in fact, be better?

A. Personal.

Q. And for anyone who is reading the deposition --

A. As well as some of the literature that's out there from other studies that are nonprospective, randomized trials.

Q. What is the prospective randomized control trial that you just mentioned?

A. It is considered the gold standard of how to end up having the best category of research done.

Q. Okay. And just returning back to what we were talking there, just so that the record is clear also, can you briefly describe the difference, if any, between anatomic benefit and symptomatic benefit?

A. You'd hope that they would be one in the same, but they're different.

Q. So could there be a scenario wherein anatomically the surgery is a complete success, but symptomatically the patient is still in pain?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: I can tell you that in my training and residency, my attendings all said it was a success so long as the vagina didn't show outside the introitus, didn't matter whether they were incontinent of feces, urine or couldn't have sex. It was a success because it went away. That to me was not an anatomical or a quality of life piece, so, yes, there's differences.

BY MR. RESTAINO:

Q. Now, we have discussed your opinion, as you wrote in your expert report, that polypropylene is inert, correct?

A. Correct.

Q. And that is your opinion, as you sit here today?

A. Correct.

MR. RESTAINO: I'm going to have marked as McKinney next an article whose title is "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants." Lead author's last name is

Clavé published 2010, International Urogynecological Journal.

(Document marked for identification as McKinney Deposition Exhibit No. 8.)

BY MR. RESTAINO:

Q. Doctor, have you seen this article before?

A. I have.

Q. And you recognize the lead author's name Clavé, if that's how it's pronounced? My apologies to the French.

A. I'm not -- personally do not know Arnaud.

Q. Do you know if he has ever held an educational position for Ethicon Europe?

A. Don't know.

Q. Prior to writing your report, did you review this article?

A. At one point in time, I read it. It's in the International Urogyn Journal. I don't know. I have to refer to on my material list, but there's so many papers that I've read. I don't believe it's part of my listing, but I read it.

Q. If you look at the conclusion of this

study and the abstract they write, "This is the first study to evaluate synthetic implants used in a vaginal approach for pelvic floor reinforcement. The study provides evidence contrary to published literature characterizing PP as inert in such application."

Did I read that correctly?

A. Yes, you have.

Q. In your expert report where you write polypropylene is inert, do you mention that there are contrary opinions in the peer-reviewed published literature?

A. I do not.

Q. In preparation for writing your report, do you recall seeing an article by a lead author Cozad titled "Materials characterization of explanted polypropylene, polyethylene, terephthalate, and expanded polytetrafluoroethylene composites: spectral and thermal analysis."

Does that sound familiar?

A. Does not.

Q. Do you recall an article Costello, et al. titled "Materials characterization of explanted polypropylene hernia meshes" published in the Journal of Biomedical Materials and Applied Materials,

August 2010?

A. I do not.

Q. Do you recall an article by Ostergard titled degradation, infection and heat effects of polypropylene mesh for pelvic implantation: what was known and when it was known in the International Urogynecological Journal, 2011.

Does that sound familiar?

A. Yes.

Q. Did you review that?

A. I've read it at one point. I did not review it in reference to this itself.

Q. None of these articles are reported upon as a contrary opinion to your stated expert opinion that polyurethane is inert, correct?

A. Well, in this particular paper, I mean, these are explants which by definition are manipulated materials that are out there. These have been pulled out of the body. They've gone through a series of chemicals to try to end up getting rid of all the tissue that's surrounding them to end up looking at them. So there's trauma that can end up being done to that entire mesh material just from the process involved to try to get these out.

Q. With that in mind, you wouldn't expect that, for lack of a better term, explantation trauma and cleansing to wash away the inflammatory cells that are about the mesh itself, would you?

A. Would I expect them to be washing out?

Q. Yes, and removing inflammatory cells?

A. I don't know their technique for how they were doing all this. Again, I'd need to read carefully into the article a little bit more thoroughly.

Q. Now, if we turn to your report, Page 8. In the middle of the paragraph or middle of the page, you have an indented paragraph that starts off with "Animal studies show that implantation of Prolene mesh elicits a minimal to slight inflammatory reaction."

Do you see that? It's on Page 8 right in the middle of your page, and if you look actually at the line above that, it looks like you're quoting directly from the IFU.

Do you see where I am, sir?

A. Yes.

Q. When you write that, what animal studies are you relying upon?

A. It was the studies that were presented

to me from the company studies.

Q. You mentioned that the Klinge study, you noted, was a dog study, and you said that in such a way like, well, it's a dog study so it doesn't directly relate to the female vagina and the human. That would apply to these dog studies or animal studies also, would they not?

A. Again, these are an attempt to extrapolate to a human experience, and it's unfortunately one of the guides that we have for doing some pre-research.

Q. And I had said or warned that we would come back to the difference between the dorsum of an animal and the complex environment of the human vagina, but there are different stresses put upon mesh when it's implanted subfascially on the back of a dog or rodent as compared to mesh that's put in a vagina, wouldn't you agree?

A. The whole purpose of placing these into that region is because there's been so much in the process of stresses and recurrences because of the anatomical nature of the vagina. There are multiple things that can affect the ability for that tissue to function while unprotected. One is the bone, two is

muscle, which is supplied by nerves, which if there's muscular damage, I don't care how good the fascia is, it's going to fall apart. So you have to augment to bypass the normal anatomical part, and, unfortunately, we're left with trying to supplement that, and it seems at this point we have a good substance. It isn't perfect. I wish we had a perfect substance, but at this point Prolene is what we've got.

Q. Now, polypropylene mesh that's implanted in the dorsum of a dog or a rat is, in fact, implanted on the transverse plane, agreed, within the back itself?

A. That's what you're saying, yes.

Q. And any stresses on it, whether north, south, east or west, in essence, are linear stresses, correct?

A. Depends.

Q. Okay. But in the female pelvis, it's multidimensional stresses, including transverse plane, frontal plane, sagittal plane. There's entirely different nonlinear stresses placed upon mesh in the pelvis as compared to the dorsum of the back, wouldn't you agree?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: I think there's stresses on all the tissue surrounding in the vagina are multiple axes.

BY MR. RESTAINO:

Q. Are you familiar with the term viscoelastic?

A. Not so much viscoelastic, but what do you mean by viscoelastic?

Q. Well, if a material is placed within the pelvis itself, would the forces on it be viscoelastic, and if you're not familiar with that term --

A. I'm not.

Q. Then I'll move on.

Is the tissue in the female pelvis homogenous or heterogenous, different tissues?

A. Hetero.

Q. And would you agree that the tissue on the dorsum of the back is homogenous. You've got fascia and you've got muscle?

A. I don't know whether that would be considered -- there are so many variations.

Q. Would you agree -- would you describe the female pelvis region as a tension-free zone?

MR. MORIARTY: Objection, form.

But go ahead.

THE WITNESS: No.

BY MR. RESTAINO:

Q. There are tensions that are present on multiple axes in the pelvis just through the process of lying down, having sex, getting up, standing, walking, correct?

A. That is correct.

Q. And all those forces can tug on mesh in multiple ways, whether it's sagittally or on frontally or transversely, correct?

A. Tugs on all of the tissues.

Q. Have you seen terms that -- declaration or claims by Ethicon that the Gynecare mesh and Prolift mesh are tension free?

A. That's a literal term, which they're trying to end up explaining that things should be non -- shouldn't be placed in for your esthetics eye's view, tight. You're supposed to put them in more relaxed.

Q. Would you agree that any claim that a mesh placed within the pelvis is tension free is just scientifically unsound?

MR. MORIARTY: Objection.

THE WITNESS: That is not -- it's a descriptive term for loosely placed versus tied tight like a trampoline. You want it to be able to have the ability to be incorporated and have some movement to it.

BY MR. RESTAINO:

Q. If you would turn now again in your expert report to Page 10, you have a paragraph "c. The Safety and Efficacy of Prolene™ Soft/Gynemesh PS Mesh."

Do you see where I am, sir?

A. Yes.

Q. And underneath it you write, "Review of scientific reports of the use of Gynemesh and pelvic reconstructive surgery date back to 2001."

Did I read that correctly?

A. That is correct.

Q. And how do you know that? Is that from your own review of the literature on PubMed?

A. It was from the presentations provided.

Q. Provided by whom?

A. Within -- as well as my own knowledge of the literature at that point.

Q. Okay. Now, you next write, and I

believe it's a person's name, it's "De Tayrac described 36 patients undergoing cystocele repair using Gynemesh with 13 month follow-up and 100% success with one mesh excision under local anesthesia for non-symptomatic exposure," reference 3.

Did I read that correctly?

A. That is correct.

Q. And looking at your reference 3 down below it does says "De Tayrac R, et al., Cystocele Repair with a Fixation-Free Prosthetic Polypropylene Mesh. Abs. 2001."

Did I read that correctly?

A. Yes.

Q. I searched for this article on PubMed and was unable to find it. Is this a published peer-reviewed article you relied upon?

A. It was an abstract.

Q. An abstract from a presentation or a poster session or -- where is the abstract from?

A. Again, that was a --

MR. RESTAINO: Matt, it's capital D-e --

THE WITNESS: It's in the list.

MR. MORIARTY: It's Number 11 in his binder.

MR. RESTAINO: Could you just share with us whether, in fact, it's an abstract.

MR. MORIARTY: It is an abstract.

MR. RESTAINO: Okay.

BY MR. RESTAINO:

Q. Are abstracts classically peer reviewed?

A. No. They are reviewed by the committees before they're allowed to be presented, and so there is a group of physicians that analyze and see whether or not it qualifies to end up being an abstract. Depending upon which meeting it's at, there could be anywhere from 70% of the abstracts that get rejected to a few more, but, no, it is not a full peer reviewed.

Q. Then, as we read, this abstract discusses 36 patients that underwent just cystocele repair using Gynemesh, correct?

A. Correct.

Q. Do you consider that a large study?

A. No.

Q. Do you consider that a small study?

A. I consider that a lot of the literature up until more recent literature have been sparse, let's put it that way.

Q. Do you consider 13-month follow-up to be

long-term follow-up?

A. No.

Q. And I'm confused when you and/or he write, "100% success with one mesh excision under local anesthesia for non-symptomatic exposure."

First, do you have an understanding what he means by non-symptomatic exposure?

A. Meaning that the patient wasn't experiencing any discomfort, maybe was or wasn't sexually active and partner wasn't, I don't have the full definition of that.

Q. Well, if there's a mesh excision for a pathological condition whether symptomatic or not, but one that requires a surgery, even under local anesthesia, I'm a little confused how you and/or he then say it's 100% success rate?

A. Well, the success depends upon your definition of it. If you're not having urinary, fecal incontinence and things are, from the patient's standpoint, comfortable, patient comes into your office, you see an exposure of a piece of -- or corner of a graft and you're able to -- much like in a case where you have native tissue and you see a suture and all you had to do was inject it and under local

anesthesia trim that edge, like you pull out a suture, that I'd consider a -- not a problem.

Since this is under local anesthesia, nonsymptomatic exposure, meaning the patient wasn't saying, oh, I've got problems. You just incidentally found it under examination, were able to take care of it, yeah, I think that it's not a problem.

Q. But, actually, states one mesh excision, doesn't say the mesh was trimmed or otherwise repaired, my reading of it is the mesh came out.

Am I reading that incorrectly?

A. I think it's incorrect.

Q. My reading is incorrect?

A. Excision meaning not explant, excision meaning removal, like I'd do an excision of the suture material that had been spit or formed a sinus tract. Sinus tract is a little bit more difficult to do in the office, but extrusion, spit.

Q. And forgive me, I'm not trying to be difficult, I haven't read the abstract itself, is it your knowledge, in fact, that De Tayrac trimmed the mesh or took out the entire mesh, or you don't know?

A. I wouldn't know. In my hands, if I was going to in the office, I would be doing an excision of

the exposed graft. If it was me in the office, saw an edge of the graft exposed past the skin, I would trim that and potentially undermine the skin there to get a deeper excision of that graft edge, and I would do it with a local injection of Lidocaine, such as described here. That's what I envision that this individual did as well.

Q. Now, you were a consultant to AMS shortly after or during or after the 2011 period of time?

A. I was.

Q. And in 2011, in addition to the update that we've been reviewing found on the web page, the FDA also published what I'll -- to differentiate what we've been looking at, I'll call this a monograph, with your permission. I'll show it to you as soon as we have it marked as next.

(Document marked for identification as McKinney Deposition Exhibit No. 9.)

BY MR. RESTAINO:

Q. Have you seen this before?

MR. RESTAINO: While you're glancing through that, Matt, how are we doing for time, do we need a break?

THE WITNESS: I need a break.

(Brief recess taken at 10:37 a.m.)

(Deposition resumes at 10:45 a.m.)

MR. RESTAINO: Well, by the stipulation and court order and by my notes, we have about an hour to go, so we'll get you out of here.

BY MR. RESTAINO:

Q. If you take a look at that document that I just handed to you, the July 2011 FDA monograph titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse," and if you turn to Page 3, you see the "Executive Summary."

You see that, sir?

A. Yes.

Q. And the second paragraph there's language that was very similar to what I will call the web-based safety update, where they write, "The FDA also conducted a systematic review of the scientific literature to learn more about the safety and effectiveness of POP and SUI using surgical mesh. The FDA determined that (1) serious adverse events are NOT rare, contrary to what was stated in the 2008 PHN, and (2) transvaginally placed mesh and POP repair does NOT

conclusively improve clinical outcomes over traditional non-mesh repair."

Did I read that correctly?

A. Yes.

Q. And you would agree that, essentially, by definition, if they did a systematic review that they are opining upon in July of 2011, the articles had to be published prior to July 2011, would you agree?

A. I would think so.

Q. And so, therefore, anything published prior to 2011 would also be available for you to review prior to writing your expert report, correct?

A. Yes.

Q. Now, does your expert report state at any time that in 2011 the FDA determined that the serious adverse events are not rare?

A. Well, again, it doesn't specify completely what the serious adverse events are, but it has a lot of interpretation there, and it doesn't -- in my expert opinion, I don't think it differs that far from what I had experienced on the non-mesh repairs, so it doesn't differentiate that aspect either.

Q. What is the objective basis for your opinion it doesn't differentiate much from the non-mesh

repair?

A. It's from readings as well as my own personal experience.

Q. And when you say "reading," can you be more specific?

A. Some of the past literature, historic literature on that as well as my experience from residency and my personal experiences with dealing with native tissue repairs.

Q. Now, when you say the past literature, historic literature, then this would be literature that was also available for the FDA to see when they looked -- when they did their systematic review, correct?

A. Well, they don't differentiate between non-mesh and mesh when they're calling serious events rare, they don't specify that this is in relationship to. It is just saying that there are some other events that are not rare.

Q. Well, the sentence above they say that their systematic review was looking at the safety and effectiveness of POP and SUI using surgical mesh?

A. Correct.

Q. So wouldn't your understanding be when

they're talking about serious adverse events not being rare, it's the serious adverse events not rare associated with the use of mesh, would you agree?

A. That is correct, but it isn't distinguishing between what goes on in native tissue as well, and that's why they've later now are recommending that we have these comparator studies between native tissue and mesh to distinguish whether there is an advantage and benefit because there's not enough good literature out there.

Q. Do you discuss this opinion and finding by the FDA in your expert report as it relates to the native repair?

A. I've discussed the fact that I didn't feel like there was a tremendous difference between meshes and native tissue repairs from that standpoint, that I felt that the mesh materials held up better than native tissue and had less recurrence rates, and from that standpoint, I've discussed that in my expert report.

Q. And what is the objective basis for your opinions that they hold up better than the native tissue and have less recurrent rates?

A. My own personal, as well as some of the

literature that I stated in there.

Q. Okay. But this literature is the peer-reviewed published literature?

A. Yes.

Q. So that literature would be available --

A. Yes.

Q. -- if it was published prior to July 2011 to the FDA?

A. Yes.

Q. Okay. Then the second aspect of this paragraph Number 2, "transvaginally placed mesh in POP repair does NOT conclusively improve clinical outcomes over traditional non-mesh repair," once again, not being capitalized by the FDA, correct?

A. That is correct.

Q. And do you disagree with the FDA in that statement?

A. I believe that there isn't as many prospective, randomized studies that are out there. There isn't as good of literature as it should be, and so the FDA had to rely on what was available.

Q. As do you?

A. As do I.

Q. If we turn to Page 8 of this monograph,

the FDA has a session there titled "Safety."

Do you see that, sir?

A. Yes.

Q. And the first bullet point is "Patients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh [7-9, 15, 16, 19-24]."

Did I read that correctly?

A. You have.

Q. Would you agree that as a physician and surgeon, your primary responsibility to your patients is their safety?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: Repeat the question again.

I was just going over this.

BY MR. RESTAINO:

Q. Sure. Would you agree that as a physician and surgeon, your primary responsibility to your patients is their safety?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: Mine is to do no harm.

BY MR. RESTAINO:

Q. That was going to be my next question.

The next bullet point by the FDA states, "Adverse events associated with transvaginally placed mesh can be life-altering for some women [13, 14, 17]. Sequelae (e.g., pain) may continue despite mesh removal."

Did I read that correctly?

A. Yes.

Q. Do you agree with the FDA that mesh-related complications can be life-altering for some women?

MR. MORIARTY: Objection, form.

Go ahead.

THE WITNESS: I believe that reconstructive surgery can be life-altering for women. I mean, they can start off with pain with relations and problems, and they can get a repair and continue with problems or worsening of their problems, especially if they have underlying pain syndromes prior to it.

It's the allodynic effect that's just take off in a negative direction, or if they have underlying other diseases, interstitial

cystitis, vulvodynia vaginismus, these are all things that are adversely affected by stress, trauma of any kind of surgery, but, yes, that it can continue after you've tried to correct whether it's native tissue or mesh.

BY MR. RESTAINO:

Q. And do you agree when they say that the sequelae may continue despite mesh removal?

A. I believe pain syndromes in women get very complex the longer they've been there, whether it's with mesh, whether it's IC, and the longer it happens, the more recruitment of nerves and the more allodynia that occurs. It's a vicious cycle.

Q. And the pain cycle you're referring to, is that a pathological syndrome in the pelvis itself or psychological syndrome?

A. Multiple facets, but it's a recruitment of silent nerves within the pelvic region that sat there dormant for years and helped regulate, so there's about 85% of the nerves in the pelvis are silent efforts.

Q. I didn't notice in your report that you indicated adverse events associated with transvaginally placed mesh can be life-altering for some women.

Do you have that opinion?

A. I have an opinion that any reconstructive surgery can end up being life-altering as far as if you don't have the perfect outcome.

Q. The next bullet point says, "Mesh-associated complications are not rare. The most common mesh-related complication experienced by patients undergoing transvaginal POP repair with mesh is vaginal mesh erosion," with multiple references listed there.

Did I read that correctly?

A. That is correct.

Q. And do you agree that the most common mesh-related complication in these women is vaginal mesh erosion?

A. The literature does agree with that.

Q. Do you state that anywhere in your expert report?

A. I've commented on mesh erosion being a part of the risk factors of putting in mesh or putting in sutures. Is that major life-altering for every single woman? In my hands, the majority of these are treated either by way of conservative management with estrogen vaginal cream, trimming in the office or, as

you called it, excision in the office under local anesthesia or, in rare situations, needing to have them removed within an OR setting.

Q. Reference 7 that the FDA relies upon as the basis for their opinions that we've been discussing about erosion, et al. is an article by Iglesia?

A. Yeah, Cheryl.

Q. Et al. "Vaginal mesh for prolapse: A randomized controlled trial."

I did not see this study in your expert report or your reliance list. Did you review it prior to writing your report?

A. I've read it in the past.

Q. This is, as we discussed earlier, a randomized controlled trial which you described, I believe, as the gold standard?

A. It's a way in which to look at literature for research.

MR. RESTAINO: I'm sorry, Matt.

MR. MORIARTY: I was going to use the word objection. Go ahead.

BY MR. RESTAINO:

Q. The next reference is reference Number 8 an article written by Withagen, et al. titled

"Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial."

Now, this one is within your reference 29, Page 16 of your report. Do you recall this article?

A. I do.

Q. And, once again, it is a randomized controlled trial, according to the title, correct?

A. Correct.

Q. On Page 16 of your report where you're using reference 29 you write that "As set forth above, the efficacy and safety of the Ethicon's Prolene Soft mesh is well-reported. It was incorporated into Ethicon's Prolift device, which was the most studied mesh kit for pelvic organ prolapse treatment, and again, the studies showed high success rates with minimal complications." Reference 29.

Did I read that correctly?

A. I was on 15 -- I was on 16, you were reading from 15. Yes.

Q. So you're using this randomized, controlled trial for the basis that the studies show a high success rate with minimal complication, yet the

FDA is using this randomized, controlled trial for the basis that the most common mesh-related complication experienced by patients undergoing transvaginal POP repair with mesh is vaginal mesh erosion, correct?

A. That is correct.

Q. Now, returning to the FDA monograph, the next reference is their Number 9 is an article by Nieminen titled "Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up."

By its title, this is another of the gold standard RCTs that you mentioned?

A. It is an attempt, yes.

Q. And this was published in American Journal of Obstetrics and Gynecology, 2010, correct?

A. Correct.

Q. I did not see this in your reference list or your expert report either. Is there a reason you did not include this randomized, controlled trial?

MR. MORIARTY: Objection, go ahead.

THE WITNESS: Just was overlooked.

BY MR. RESTAINO:

Q. Do you know the -- have you ever reviewed this article?

A. I'm sure I have read it briefly, but I can't recall it right today.

Q. Sure. The next reference relied upon by the FDA there is Number 15, Rardin, et al. titled "New considerations in the use of vaginal mesh for prolapse repair" published in the Journal of Minimal Invasive Gynecology, 2009.

Did I read that correctly?

A. Yes.

Q. I did not see this one in your expert report or your reliance list either.

Do you recall reviewing this article?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: I can't remember the article, and I know Dr. Rardin very well, but I can't recall what was mentioned within that article.

BY MR. RESTAINO:

Q. Okay. The next reference being relied upon by the FDA is Number 16, Miller D, et al. "Prospective clinical assessment of the transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse - 5 year results," published in FPMRS, 2011.

Now, I did see that you listed this article on Page 12 of your report, and describing the article you write that the mesh erosion rate in this study was 19%.

Do you recall that?

A. Yes.

Q. Do you consider 19% to be a high complication rate?

MR. MORIARTY: Objection, form.

Go ahead.

THE WITNESS: It's not so much that it's a complication. It's an exposure of which in my hands, majority of those down to less than 5% are cured just by way of treating with hormone replacement, estrogen replacement, and so is that a large percentage? It depends upon the treatment that was accomplished with it.

BY MR. RESTAINO:

Q. You know, if we were to exclude life-threatening conditions and/or trauma, can you think of a surgical procedure that carries with it a known 19% complication rate?

A. There's been reports with native tissue that have caused dyspareunia, I mean, that was -- the

standard was about 20% to 40% in the literature for just regular native tissue repairs. It's unfortunate but it's a very difficult problem that women face, and it's the reason why we started looking for any way in which we could end up helping to prevent recurrences of these things, and that's why this whole investigation of utilizing these products and Ostergard was using Gortex because of the frustrations, so he was putting in that before we knew that that was a nasty material. It's just a very tough time.

My mentor is Glenn Hurt. He and I taught together in a number of courses. He was using fascia from cadaverics but that absorbed and it was also difficult and also came with the risk factors, but this is all evolving. It's a very important avenue to try to end up helping these women, and this was the best thing.

Q. But at least as of July 2011, it was the FDA's opinion that the complications with mesh-associated repair exceeded the complications with native repair, wouldn't you agree?

MR. MORIARTY: Objection.

THE WITNESS: It didn't say that.

MR. MORIARTY: Go ahead.

THE WITNESS: They didn't say that.

BY MR. RESTAINO:

Q. Okay. Continuing on looking at this section, then they have references 19 to 24, and if you just turn to the back or to their reference list, you can see I'm not going to go through each one of them, but 19 through 24, they're the six articles there, can you tell me if any of those articles are mentioned in your expert report?

MR. RESTAINO: You know, let me point out one thing and apologize, this one does have a Maher, C et al., which is different from a Maher that's listed in your reliance list, but, Matt, I believe you said there was another Maher included. Just so the record is clear, are they one in the same as here?

MR. MORIARTY: The Maher referred to in footnote 22 to Exhibit 9 was published in 2010. The Maher I referred to at the beginning of this deposition concerning his reliance list and the Notice of Deposition was a 2016 update to footnote 22.

MR. RESTAINO: Okay.

BY MR. RESTAINO:

Q. So, again, Doctor, going back to my original question then. For references 19 through 24, do you recognize any of those articles which the FDA relies upon?

A. Not in my review, I know at least one of those papers.

Q. Okay. If we return to the monograph, Page 8, the fourth bullet point the FDA writes, "More than half of the women who experienced erosion from non-absorbable synthetic mesh required surgical excision in the operating room. Some women required two to three additional surgeries," reference 23.

Did I read that correctly?

A. Yes.

Q. Do you have any objective basis for which to disagree with the FDA with their analysis that half of the women who experienced erosion from non-absorbable synthetic mesh required surgical excision in the operating room. Some of the women requiring two to three additional surgeries?

MR. MORIARTY: Objection, form.

THE WITNESS: I don't know exactly where they -- from one paper they're citing only Abed.

BY MR. RESTAINO:

Q. Is that Abed study mentioned in your expert report or your reliance list?

A. I did not, so I can't comment explicitly on that. I can only comment from my own experience, and that definitely is not what Abed -- that statistic seems rather high.

Q. Would you agree that the Abed article, and if you're looking at the reference 23, which I'll come back to, 23 Abed et al., "Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review." International Journal of Urogynecologic Journal, 2011.

This is a peer-reviewed systematic review, correct?

A. It's just a review.

Q. But with it being published in this journal, do you subscribe to this journal?

A. Yes, I do.

Q. Have you ever published in this journal?

A. Yes.

Q. Is it your understanding it's a peer-reviewed journal?

A. Yes.

Q. Safe to assume that this systematic review was peer reviewed?

A. Yes, but it's not his own research, it's just a review article.

Q. Understood. And your analysis of your own patients when you state that in your hands the complication rate is not what the FDA and/or Abed is reporting, is your personal experience peer reviewed?

A. No.

Q. The next bullet point is "Mesh contraction, causing vaginal shortening, tightening, and/or vaginal pain in association with transvaginal POP repair with mesh, is increasingly reported in the literature," two references, 13 and 17.

Did I read that correctly?

A. Yes.

Q. If you look at 13, it's lead author Caquant, title of "Safety of Transvaginal Mesh Procedure: retrospective study of 684 patients."

Now, you discussed this on Page 12 of your report, correct?

A. Yes.

Q. However, the FDA is relying upon this

article as one of the articles to support their opinion that -- regarding the mesh contraction, correct?

A. That is what it's saying in here, yes.

Q. And yet you state in your expert report that the mesh itself does not contract, correct?

A. Yes.

Q. Did you -- looking at reference 17 it's by Feiner, B et al., and this article is titled "Vaginal mesh contraction: definition, clinical presentation, and management." Obstetrics Gynecology, 2010.

Have you discussed the Feiner article?

A. I have not.

Q. Do you recall seeing the Feiner article?

A. I don't recall it.

Q. Now, if we look, returning to the FDA monograph, the next bullet point is "New onset SUI has been reported to occur more frequently following mesh augmented anterior repair compared to traditional anterior repair without mesh," reference 12.

Did I read that correctly?

A. Yes.

Q. Reference 12 is a paper by Altman, et al. titled "Anterior Colporrhaphy versus Transvaginal

Mesh for Pelvic Organ Prolapse," published in the New England Journal of Medicine, 2011.

And, once again, you do list this article in that large reference number 29 on Page 16 of your report.

Do you recall that?

A. I didn't remember the Altman name.

Q. The language you use starts, as I recall, on Page 15, continues on to 16 and then it's reference 29.

A. Okay. Yes.

Q. Now, the FDA is relying upon the Altman study and the Altman study alone to report that "New onset SUI has been reported to occur more frequently following mesh augmented anterior repair compared to traditional anterior repair without mesh," but your expert report does not state that, does it?

A. It does not.

Q. Do you disagree with that opinion by the FDA?

MR. MORIARTY: Objection to form.

THE WITNESS: I just can end up noting my own personal aspect as well as some of the other literature that I've read it does not

support that entirely. This is only one reference. There's so many others that are out there that showed decreases, including some of my own abstract data.

BY MR. RESTAINO:

Q. The next bullet point we sort of touched upon when we were discussing the complication rate with mesh versus non-mesh repair, and the FDA states here, "Transvaginal surgery with mesh to correct vaginal apical prolapse is associated with a higher rate of complication requiring reoperation and reoperation for any reason compared to traditional vaginal surgery or sacrocolpopexy," and they have reference 20.

If you look at 20, article by Diwadkar, GB, and it's titled "Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review," and I think we touched upon this, this is not mentioned in your expert report, correct?

A. Right. I'm fairly familiar with this. I can't comment directly today, but I know I've referenced this before, in that there's actually less complications from vaginal mesh than there is from, I think, abdominal approaches, and there's also a discrepancy with hysterectomy or without hysterectomy,

but I need to review that paper again.

Q. That is discussed in your expert report?

A. It is not. It may appear in one of the presentations that you'll be getting subsequently.

Q. The final bullet point on Page 8 of the FDA monograph states, "Abdominal POP surgery using mesh (sacrocolpopexy) appears to result in lower rates of mesh complications compared to transvaginal POP surgery with mesh, with the median vaginal mesh erosion rate reported at 4 percent within 23 months of surgery," and that's reference 22.

Do you agree with the FDA's opinion there?

A. Again, it depends upon whether this was done with or without hysterectomy. There's a vast difference between a sacrocolpopexy without hysterectomy and with.

Q. The reference 22 is for another Maher, "Surgical management of pelvic organ prolapse in women," published in the Cochrane database systematic review, 2010.

First, do you know what the Cochrane library is?

A. Yes.

Q. What can you tell us about it?

A. It's a compilation of complications that have been reported, and I'm not sure whether it's through the MAUDE database that added to it, but the Cochrane has its own way of looking at things. It usually does not include native tissue kind of repairs. It's usually something different.

Q. I guess it would depend on what the researchers want to look at, correct?

A. That is correct.

Q. And, in fact, the Cochrane Group they're known for doing their systematic reviews or meta-analyses of randomized, controlled trials, correct?

A. Yes.

Q. Is this Maher paper published in the Cochrane database systematic review included in your expert report?

A. I don't believe so.

MR. RESTAINO: Okay. Getting towards the end, how are we doing time-wise?

MR. MORIARTY: About half an hour.

MR. RESTAINO: Perfect.

BY MR. RESTAINO:

Q. The next section is "Effectiveness," and the FDA writes that "The literature review found that while transvaginal POP repair with mesh often restores anatomy, it has not been shown to improve clinical benefit over traditional non-mesh repair, as evidenced by the following key findings: Transvaginal apical or posterior repair with mesh does not appear to provide any added benefit compared to traditional surgery without mesh," references 5-8, 18, 22 and 24.

Did I read that correctly?

A. Yes.

Q. Now, in your expert report, I was not able to see anywhere where you state that 2011 the FDA was warning that transvaginal POP repair with mesh, while restoring anatomy, has not been shown to improve clinical benefit over traditional non-mesh repair.

Do you disagree with the FDA in their opinion here?

MR. MORIARTY: Objection, form.

THE WITNESS: They are purely using a -- that's why they've requested the 522s to be done looking at native tissue versus implantation of meshes at this point is they don't have it completely down pat. Some of

these papers are before -- one of them in particular is not even using the Prolene. It's a polyglactin 91 mesh, that was Peter Sand's paper.

BY MR. RESTAINO:

Q. Okay. Any of these references, 5 through 8, 18, 22, 24, do you mention them in your expert report?

A. Some of them.

Q. Now, the following bullet point is "Only two RCTs compared multi-compartment repair (including apical repair) with mesh to traditional repair, and neither found a significant improvement in effectiveness with mesh augmentation [7, 8]. A systematic review of vaginal mesh kits for apical repair found they appear effective in restoring apical prolapse in the short-term, but long-term outcomes are unknown," with reference 21.

Now, the two randomized, controlled trials they allude to we've already discussed, and that's the Iglesia and Withagen papers, correct?

A. Yes.

Q. And neither one of these are in your expert report, correct?

A. I'm not sure about Iglesia. No.
Q. I'm sorry, Doctor, did you answer?
A. I said no.
Q. Okay. The next section by the FDA is titled "Limitations of Existing Literature."
Do you see that?
A. Sorry. My brain is still back in the -- where am I at now?
Q. Page 9 of the FDA monograph.
A. Yes.
Q. And do you see they have a section there where they discuss limitations of existing literature, Page 9 of the FDA monograph, right above "Summary of Key Findings."
You see that, sir?
A. Mm-hmm.
Q. And the FDA lists six bullet points there, correct?
A. Mm-hmm.
Q. Would you agree --
A. Yes.
Q. -- that any limitation of the existing literature in the systematic review by the FDA would also apply to any review of the literature that you've

conducted?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: Let me read over.

MR. RESTAINO: Of course.

THE WITNESS: (Reviewing document.)

Yes, I'm ready.

BY MR. RESTAINO:

Q. The question was would you agree that any of these recognized limitations that apply to the FDA's review of literature would also apply to your review of the literature?

A. Yes.

Q. On Page 19 of your expert report, the bottom paragraph you write, "It is comforting as a surgeon to be using a product that is known to have the largest amount of peer-reviewed data from multiple institutions substantiating a safe, reliable, reproducible technique and material. Prolene has been around for 50 years, been safely used in various applications, and the body's reaction to material is known."

Did I read that correctly?

A. Yes.

Q. Now, we've just gone through a litany of peer-reviewed articles, systematic reviews, meta-analysis and randomized, controlled trials which the FDA has relied upon in 2011 when they sent out their updated warning, none of which are included in your expert report, correct?

A. There were some.

Q. On Page 20 of your report the first sentence, "Complications are usually surgery-related and not mesh-specific." There's no reference for that.

What is the objective basis for that opinion?

A. Definitely from my experience and my drawing on my own experience teaching my fellows as well as teaching other surgeons techniques, and the complications that are associated with reconstructive surgery has a lot to do with the techniques and not so much on the mesh.

Also, the limited knowledge of a lot of the people that I've trained in anatomy, they come to me taking my anatomy courses, and they have no idea of what they're putting together. Most of them have no idea of what -- if I'm telling them I'd like you to describe what the structures are that you're trying to

put together, they say, well, I'm going to take some of this stuff and put it to that stuff. Hopefully, by the time they end up finishing my education for them that they come out with the knowledge that that stuff on the anterior wall is pubocervical fascia and it's being attached down to the arcus tendineus, and you're attaching it to the fascial ani levator muscles and how they interact.

But it really comes down to the surgical techniques matter on successes of the surgery, understanding anatomy is huge in any kind of reconstructive work. So the meshes themselves can't be blamed for things as well as sutures. It's surgical skills and understanding that go into these things a lot more. So it's a lot more than just my own personal hands-on experience, but through years of teaching other surgeons, there are a lot of variations in the abilities.

Q. Yet in the 2011 FDA monograph, it's the FDA's opinion that the complications are due to the mesh, correct?

A. It may not be just from the mesh. It's from the ability of those surgeons to place the mesh in the proper position. So it's not so much the mesh but

the instrument, and I can go out and I can play golf and I can blame it on my clubs and go out and buy another golf club and I'd still play just as badly. If I'm a bad surgeon or if I'm not as efficient or if I place something in the wrong plane, I'm going to end up having some issues. It's not so much the material, it's the actual operator.

Q. It's your opinion that all pelvic surgeries have similar risks and the introduction of the Prolene PS mesh has served to decrease the complications when compared to various techniques?

A. I feel that it's decreased the complication of recurrences, that's for sure, and I am the referral base for a lot of the recurrences, so maybe mine is biased out there, but I get the failed times one, two of native tissue or other attempts, and so I'm having to end up being the person who ends up seeing the repercussions.

So from that standpoint, I have a bias that there's problems, and there are problems with recurrences and pain and shortening of the vagina, all due to whatever happened prior, whether it's the tissue of the patient or the surgical technique.

Q. Final couple questions, Page 21, the

large paragraph starting at the top of the page, four lines down towards the right center of the line that you write -- I'm sorry. Let's just read the paragraph.

"Furthermore, the FDA issued a Public Health Notification in 2008 regarding the use of synthetic mesh for treatment of prolapse and incontinence. It alerted healthcare practitioners to 'complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI).' It noted that the major complications were rare, but could have serious consequences, and that the 'most frequent complications included erosion through the vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence.'"

Did I read that correctly?

A. Yes.

Q. Now, in this report to the Court, is there a reason why you quoted the public health notification of 2008 when the FDA described the serious complications as rare, but not the July 2011 report where the FDA reversed course and said these serious complications are not rare?

A. Well, my main portion of the report was

because I was dealing with not the kits as much as the material, and so this was commenting more on the -- I felt was geared more towards the actual materials of Prolene and Prolene Soft that were being introduced, and that's what I was expected to report on.

If I had to do everything from soup to nuts with graft materials, slings and Prolifts and Elevates and everything all the way through, I would definitely have put in a lot more. This report would have been probably about -- a lot more.

MR. RESTAINO: Okay. I don't have any questions.

MR. MORIARTY: I have a few.

BY MR. MORIARTY:

Q. Let's go in reverse order here, Dr. McKinney.

Page 20 of your report, this top sentence that you were asked some questions about a few minutes ago, to the best of your memory, are there references in the peer-reviewed medical literature agreeing with your opinion that surgical technique is a substantial factor in the safety and efficacy of pelvic surgery using polypropylene mesh augmentation?

A. Yes.

Q. Is it also discussed at continuing medical education conferences?

A. Absolutely.

Q. Now, was your focus in drafting this report on Gynemesh PS?

A. Gynemesh and Gynemesh PS.

Q. Is that the sheet mesh that you do not consider to be a kit?

A. That is correct.

Q. And after the launch of Prolift and the mesh kits of competitors in and after 2005, did the use of Gynemesh PS transvaginally for the repair of pelvic organ prolapse decrease in its frequency?

A. No.

Q. So you've been asked questions about Exhibit 5 and Exhibit 9 from FDA, correct?

A. Correct.

Q. Was the focus of these on transvaginal approaches to pelvic organ prolapse, the primary focus of these two?

A. Yes.

Q. Okay. Now, was Gynemesh as a product restricted in any way by its IFU to transvaginal approach?

A. No.

Q. Was Gynemesh PS used regularly by surgeons like you through transabdominal surgery to perform abdominal sacrocolpopexy?

A. Yes, for years and years.

Q. Was abdominal or is abdominal sacrocolpopexy considered the gold standard for uterovaginal prolapse?

A. It is, as well as extending that even further for failures of apical support.

Q. Is it safe and effective for that?

A. Yes, although it does have its risk factors as any kind of surgeries.

Q. Is abdominal sacrocolpopexy typically used to repair either a cystocele or rectocele?

A. Not in and of itself, unless you extend the attachments further down anterior or posterior.

Q. In Exhibits 5 and 9 -- I'm sorry. Let's just talk Exhibit 9. These citations in the back, Mr. Restaino was asking you about, do you know whether FDA made any effort in its bibliography list to separate out references to kits like Prolift or Elevate from references regarding either the transvaginal or transabdominal use of a product like Gynemesh PS?

A. Not that I am looking at.

Q. So when you drafted your report and helped us put together the reliance list, were we trying to focus primarily on Gynemesh PS to the extent that we could?

A. Yes.

Q. Prior to the launch of Gynemesh PS, were you using polypropylene mesh in various applications in pelvic surgery?

A. Yes.

Q. Do you have publications and abstracts that you presented at CME meetings about that?

A. Yes.

Q. Did you start using Gynemesh PS when it was launched in 2001 or '02?

A. I did.

Q. Did you use it transvaginally to repair pelvic organ prolapse?

A. Yes.

Q. Did you use it transabdominally for apical repairs?

A. Yes.

Q. Do you have abstracts that you did and presented at CME conferences regarding the results of

your use of Gynemesh PS transvaginally for the repair of pelvic organ prolapse?

A. Yes.

Q. So when you talk about your personal experience, is that actually documented somewhere with the use of these very products in abstracts and CME conferences?

A. Yes.

Q. Did you later update your Gynemesh PS transvaginal POP repair abstract with additional Gynemesh PS cases, plus a handful of Prolift cases?

A. I did.

Q. And was that a separate abstract presented at a separate CME conference?

A. Yes.

Q. Did you later after you switched to the AMS Elevate product do an abstract documenting your results in transvaginal POP repair with that product?

A. Yes.

Q. Was that presented at a CME conference?

A. Yes.

Q. So, again, when you talk about the body of your experience with these procedures from, say, 2001 through 2012 or '13, that was documented in

abstracts and at CME conferences?

A. Yes.

Q. You were asked questions about this Clavé article. I have just a couple questions about this.

You read this as recently as yesterday; is that true?

A. Yes.

Q. Is it true that when they put these explanted specimens under scanning electron microscopes, less than half of them showed degradation?

A. That is correct.

Q. Did they question whether oxidation even occurred in a sentence saying, if oxidation occurs in these prosthetics, it takes place in the amorphous zones and crystallinity is preserved; did they say that?

A. Obviously, it's listed right there.

Q. Did they have several hypotheses about what they thought was degradation of polypropylene mesh?

A. Yes.

Q. Were they able to confirm any of their hypotheses in this study?

A. No.

Q. Did you ever participate in hernia surgeries in which Prolene mesh was used?

A. Yes.

Q. You were asked some questions about degradation. Have you seen studies which showed no loss of molecular weight or tensile strength in explanted mesh from dog specimens?

A. Yes.

Q. You were asked some questions about Exhibit 7, this Klinge article. First, is this study mesh used for hernia repair?

A. I'm confused.

Q. The Klinge article, Exhibit 7.

A. Yes.

Q. Did they study hernia meshes?

A. Yes.

Q. Was one of them Marlex?

A. Yes.

Q. Was it an experimental study in dogs?

A. It was.

Q. How many dogs?

A. Ten.

Q. Now, it says here in the abstract,

"Results: After 4 weeks the area of mesh in the monofilament group was reduced."

Do you see that?

A. Yes.

Q. Doesn't say the mesh was reduced, it says the area, correct?

A. That is correct.

Q. Last sentence in this conclusion does it say, "Meshes with big pores are less likely to fold and improve compatibility"?

A. That's what it says in its conclusion.

Q. Is it your understanding that Gynemesh PS is a large pore, lightweight mesh?

A. Yes.

Q. Are there risks of infection with any surgery in the pelvis?

A. Yes.

Q. Are there thousands of articles examining the use of mesh in the augmentation of pelvic organ prolapse surgery?

A. Yes.

Q. Whether it's transabdominal or transvaginal?

MR. RESTAINO: Objection.

THE WITNESS: Yes.

BY MR. MORIARTY:

Q. Has there ever been any Level I evidence to show that the incidence of infection is increased in mesh surgeries over native tissue repairs?

A. No, there is not.

Q. Last area I want to ask you about is Exhibit 5, this FDA.

Now, when we asked you to render opinions in this case, did we ask you to render opinions to a reasonable degree of medical probability?

A. Yes.

Q. Do you know the difference between reasonable degree of medical probability and speculation and possibilities?

MR. RESTAINO: Objection.

THE WITNESS: Yes.

BY MR. MORIARTY:

Q. Let's go to Page 2 of this FDA document. Fourth paragraph on the page, third line, does it say, "Furthermore, it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair"? Does it say that so far?

A. Yes.

Q. So it is not clear, is that a -- do they have a citation or is that any sort -- expressed to any sort of reasonable scientific certainty there?

A. That is not.

Q. And then it refers to "in all patients," correct?

A. Yes.

Q. Is there ever, from your experience, something that applies either in the effectiveness realm or the safety realm to every single patient?

A. Never.

Q. And then it says, "with POP and it may expose," is it your understanding that may is speculation, or is it reasonable degree of probability?

MR. RESTAINO: Objection.

THE WITNESS: Speculation.

BY MR. MORIARTY:

Q. Thank you.

In the abstracts that you did about Gynemesh PS and then Elevate, were the meshes both safe and effective?

A. Yes.

Q. Were the complication rates low?

A. Yes.

Q. All right. Let's go down further to this paragraph towards the bottom. It begins with, "in order to better understand."

You see where I am?

A. Yes.

MR. RESTAINO: Matt, I'm sorry, are you looking at the 2008 or 2011?

THE WITNESS: I'm looking at Exhibit 5.

MR. MORIARTY: The one you spent a lot of time on.

THE WITNESS: The '11.

BY MR. MORIARTY:

Q. It says here, "The review showed that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair."

Do you see that?

A. Yes.

Q. So this is referring to the subjective category of patient satisfaction, is it not?

A. That is correct.

Q. But it did not show that mesh was less efficacious, did it?

A. No, it did not.

Q. Last question on this page, there's a bullet point at the bottom about mesh erosion. Is it your experience that that is the unique complication of transvaginal mesh or mesh in general is the erosion?

A. That's any kind of permanent material, so suture and mesh, yes.

Q. Next page, top bullet point refers to mesh placed abdominally versus transvaginally.

Do you see that?

A. Yes.

Q. So you could place Gynemesh PS transabdominally or transvaginally, correct?

A. Yes.

Q. The first paragraph after the bullet points, it's talking about their literature review, right?

A. Yes.

Q. It says, mesh review -- or I'm sorry -- "mesh erosion can require multiple surgeries."

Do you see that?

A. Yes.

Q. Does can in any way quantitate the risk?

A. Not at all.

Q. In your experience and from the Level I

evidence, is it more likely that patients will require multiple surgeries to repair a mesh-related complication or not?

A. It is not.

Q. And is this referring to just some women?

MR. RESTAINO: Objection.

BY MR. MORIARTY:

Q. Right there. Is that what it says?

A. Yes, that's what it says.

Q. And not all women who have mesh have complications, correct?

A. That is very correct.

Q. Is it a fact that there is no complication of pelvic organ prolapse surgery or any mesh complication that exceeds anywhere near 50% of the women on whom are operated, correct?

MR. RESTAINO: Objection.

THE WITNESS: Absolutely.

BY MR. MORIARTY:

Q. It says here, "Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain."

Do you see that?

A. Yes.

Q. Are vaginal shortening, vaginal tightening and vaginal pain potential risks and complications of native tissue repairs for pelvic organ prolapse?

A. Yes.

Q. Next paragraph, "both mesh erosion and mesh contraction may lead to," and then it lists a number of complications. Anywhere in there is it saying that these are likely to occur?

A. No. Again, any time that you say may, it's a guess.

Q. In your experience, supported by what you have published in our own abstracts and presented at CME and the Level I evidence, are any of these complications that are listed in this particular paragraph frequent?

A. No.

MR. MORIARTY: That's all I have.

BY MR. RESTAINO:

Q. Just a few follow-up questions.

You've been asked about several of the abstracts that you've written and given at CMEs, correct?

A. Yes.

Q. Are any of those abstracts peer-reviewed articles published within the peer-reviewed literature?

A. They are not.

Q. When you were asked about the area of the mesh shrinking versus the mesh itself, the area of mesh is determined by its width times its length, correct?

MR. MORIARTY: Objection, form.

Go ahead.

THE WITNESS: That's a difficult question, because I can take and roll up a wad of paper and it will change its shape.

BY MR. RESTAINO:

Q. Let me withdraw the question. I just want to clarify for the record. When we're talking about the area of mesh, we're not talking about the tissue, human tissue that's around the mesh, that area, we're talking about the size area of the mesh itself, correct?

MR. MORIARTY: Objection, form.

THE WITNESS: Again, it's hard to distinguish between the two because the human tissue that in-grows into the mesh will change

the form of the area because of the scar tissue associated with the healing process. It's not necessarily the graft matrix that changes the -- its size but it's the actual material that the body lays down causes the changes in size. Just like with any surgical correction, scar tissue shrinks.

Q. The Gynemesh PS mesh, that is a form of monofilament polypropylene mesh, correct?

A. Yes.

Q. Did you see anywhere in any of the updates from the FDA in their monograph, as we referred to it today, or in the peer-reviewed medical literature that Gynemesh PS is excluded or different from the analysis that's performed regarding all polypropylene meshes?

A. There was no exclusion or inclusion.

Q. And if you turn to the actual 2011 monograph. Well, first, you were asked a number of questions regarding Exhibit 5 regarding mesh contraction, but none of these paragraphs have references on them, correct?

A. Correct.

Q. This same language we discussed is in

the monograph with references to support their opinions, correct?

A. I'd have to look at it again.

Q. And as we've determined, some number of these, whether it's -- some number of these studies were not included in your expert report, correct?

A. That is correct.

Q. If we can turn to that 2011 monograph.

MR. MORIARTY: Talking about Exhibit 9, correct?

MR. RESTAINO: Correct.

BY MR. RESTAINO:

Q. If you would turn to Page 9 of that document and if you see above "Limitations of Existing Literature," there's a bullet point wherein the FDA writes, "Compared to traditional vaginal surgery without mesh, abdominal apical prolapse repair with mesh (sacrocolpopexy) results in less recurrent prolapse, although it has not been shown to reduce the rate of repeat surgery for recurrent prolapse," with reference 22.

Did you see where I just read that from?

A. Yes.

Q. So the FDA in doing their systematic

review was aware of the fact of both transvaginal and abdominal approaches using mesh, correct?

A. That is correct.

Q. And they did not exclude the abdominal approach for this abdominal apical prolapse repair from their analysis, did they?

MR. MORIARTY: Objection, form.

Go ahead.

THE WITNESS: In this one instance, yes.

BY MR. RESTAINO:

Q. Okay. And paragraph -- I mean reference 22 is the Maher article that we discussed that's published in the Cochrane database systematic review, 2010, correct?

A. Correct.

Q. And this was not included in your expert report or reliance list, correct?

A. That is correct.

Q. Do you know if the Cochrane analysis excluded the abdominal approach and just looked at transvaginal?

MR. MORIARTY: Objection.

Go ahead.

THE WITNESS: According to this

paragraph, but I don't have it in front of me, so I can't comment on that right now.

MR. RESTAINO: Okay.

MR. MORIARTY: Just one follow-up.

BY MR. MORIARTY:

Q. Getting back to this Klinge article, was one of the primary methods by which they measured shrinkage or contracture by taking radiographs?

A. Yes.

Q. When you take a radiograph of the pelvis that has mesh in it, can the radiograph distinguish between the mesh, the mesh fibers and the tissues that have grown within the mesh interstices itself?

A. It would be -- I'm not an expert on that; however, it would be very difficult to end up seeing that.

MR. MORIARTY: Okay. That's it.

MR. RESTAINO: Okay. That's it.

(Witness excused.)

(Deposition concluded at 12:00 p.m.)

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C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Shorthand Reporter, Certified LiveNote Reporter and Notary Public, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR
CSR #XI01497 Notary Public

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ACKNOWLEDGMENT OF DEPONENT

I, TIMOTHY BRIAN McKINNEY, M.D., do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

TIMOTHY BRIAN McKINNEY, M.D. DATE

Subscribed and sworn to before me this

_____ day of _____, 2016.

My commission expires:_____

_____

Notary Public